ROBOSEP™

The Fully Automated Cell Separator

CATALOG #20000

USER MANUAL

StemCell Technologies Inc
The Cell Experts™ | www.stemcell.com

FOR RESEARCH USE ONLY

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August 2005
Catalog # 28940

Safety Information - Warnings

This instrument is intended for research use only and must be operated by trained professionals.

To ensure adequate cooling of RoboSep™, place it on a clean, flat surface, and be sure that there is at least 10 cm (4 inches) of clearance around each side of the instrument. Make sure that the bench space is free of any foreign objects or debris that could block the fan vents.

Always connect the power supply to a 3-prong, grounded AC outlet rated 4A, 110–240 V using the AC power cord provided with RoboSep™. Do not use an adapter to a two-terminal outlet. Before plugging the instrument in, be sure that the correct fuses are installed. Use two 4A, 250V, 5 x 20 mm Type T fuses.

Electrical devices pose the risk of electric shock. To reduce the risk of shock, do not open any covers that are fastened with screws. While RoboSep™ is designed to withstand spills on its exterior surface, do not allow fluids to enter the interior of the instrument. In the event of such a spill disconnect the power cable before cleaning up.

Do not operate RoboSep™ in extreme humidity or in conditions that can create condensation. Protect the instrument against dust and moisture, and avoid physical shock and strong forces. Do not exert excess pressure on the screen.

The EasySep® magnets on the RoboSep™ carousel generate strong magnetic fields. Keep away from computer discs, pacemakers, watches and other objects that respond to magnetic fields.

Always operate RoboSep™ with the lid down.

In case of malfunction, call StemCell Technologies Inc for service. Contact information is located at the back of this manual. Do not attempt to fix the instrument yourself. Never remove the outer casing of RoboSep™. There are no user-serviceable parts inside the instrument.

Notice

RoboSep™ is designed and certified to meet UL-CAN/CSA-CENELEC EN 61010-1 safety requirements. Safety certified products are safe to use when operated in accordance with the user manual. This instrument should not be modified in any way. Alteration of this instrument will:
- Void the manufacturer's warranty,
- Void the 61010-1 safety certification,
- Create a potential safety hazard.

This product conforms to the "Class A" standards for electromagnetic emissions intended for laboratory equipment applications, according to FCC (Part 15) and CENELEC EN 61326. It is possible that emission from this product may interfere with some sensitive appliances when placed nearby or in the same circuit as these appliances. The user should be aware of this potential, and take appropriate measure to avoid interference.

StemCell Technologies Inc is not responsible for any injury or damage caused by the use of this instrument for purposes other than those for which it is intended, or by modifications of the instrument or software not performed by StemCell Technologies Inc or an authorized agent.

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1. Introduction

RoboSep™ is a laboratory instrument that fully automates EasySep® immunomagnetic cell separation. EasySep® is a column-free magnetic cell separation technology that enables both positive and negative selection of desired cells from virtually any species. Using an integrated color touch screen, RoboSep™ can be programmed to purify cells from up to 4 samples at once. The user simply loads the correct consumables as indicated on the touch screen and presses "Run". RoboSep™ then automatically executes the EasySep® immunomagnetic labeling and magnetic separation steps using disposable pipette tips.

RoboSep™ is intended for research applications only. Please make sure that you have read the Safety Information – Warnings section of this manual, located on page ii, before using the instrument.

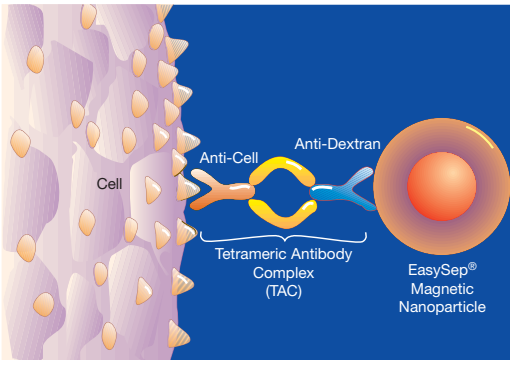
1.1 System description

1.1.1 EasySep® Magnetic Cell Separation Technology

EasySep® is a powerful immunomagnetic cell selection procedure that combines the specificity of monoclonal antibodies with the simplicity of a column-free magnetic system. EasySep® can be used as either a positive or a negative selection approach to purify your cell of interest. With EasySep® positive selection, highly purified cells are obtained by targeting the cells of interest with antibodies to a specific cell surface antigen. These targeted cells are crosslinked to EasySep® magnetic nanoparticles via StemCell's patented TAC technology (Figure 1) in a standard FACS tube. The tube is then placed directly in a specially designed EasySep® magnet. This handheld magnet is gently inverted to remove the cells that are not bound to the magnetic nanoparticles. To obtain a highly purified cell population, the cells remaining in the tube are resuspended and separated twice or more, then easily collected by removing the tube from the magnet (Figure 2). For negative selection applications, unwanted cells are targeted for depletion using a cocktail of monoclonal antibodies directed against specific cell surface antigens. The labeled unwanted cells are then crosslinked to EasySep® magnetic nanoparticles in a standard FACS tube. The tube is placed directly in the specially designed EasySep® Magnet. This handheld magnet is gently inverted to remove the desired cells which are not bound to the magnetic nanoparticle complexes. The unique EasySep® magnet generates a high gradient magnetic field in the interior cavity that is strong enough to separate cells labeled with EasySep® nanoparticles without the additional magnetic field gradients provided by a column matrix. Unlike larger microparticles used with other column-free systems, the EasySep® nanoparticles do not interfere with subsequent FACS analysis and do not need to be removed.

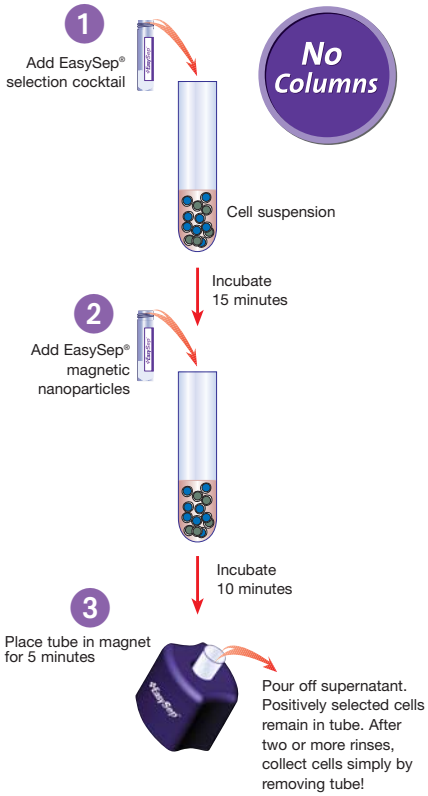
In addition to the range of EasySep® selection cocktails that are currently available to select specific cells, other cocktails can be easily prepared using the flexible TAC technology. Any mouse IgG_1 anti-cell antibody can be incorporated into TACs to select or deplete your cell of interest. Prepare your own custom cocktail with "Do-It-Yourself" TACs or request a custom cocktail. Plus, virtually any cell type from any species can be selected using PE, Biotin, FITC, or APC selection cocktails, and your own appropriately labeled antibodies.

Figure 1 – Schematic drawing of EasySep® magnetic labeling of human cells



TACs are comprised of a specific anti-cell antibody (which recognizes the target cell) bound to an anti-dextran antibody (which recognizes the magnetic nanoparticle) using a pair of rat anti-mouse IgG_1 "linking" antibodies.

Figure 2 - EasySep® procedure for positive selection


1
Add EasySep® selection cocktail
No Columns
Cell suspension
Incubate 15 minutes
2
Add EasySep® magnetic nanoparticles
Incubate 10 minutes
3
Place tube in magnet for 5 minutes
Pour off supernatant. Positively selected cells remain in tube. After two or more rinses, collect cells simply by removing tube!

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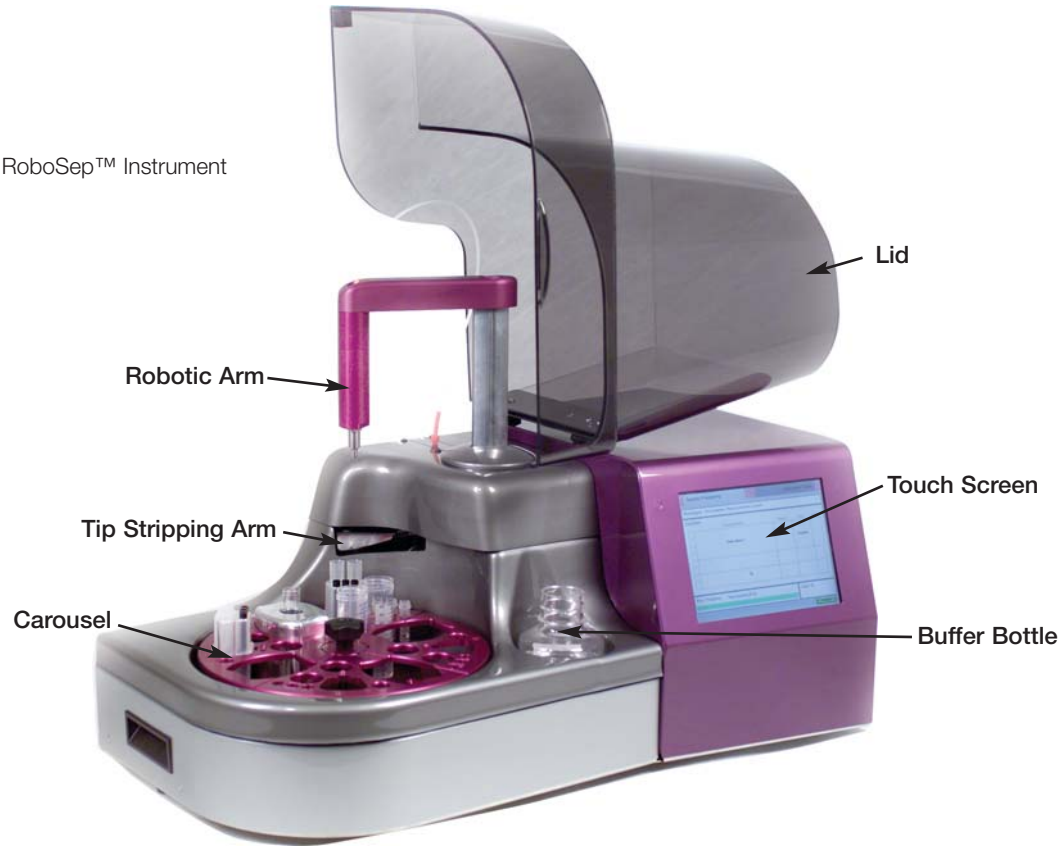
1.1.2 Robotic System Overview

RoboSep™ is a pipetting robot comprising 4 main mechanical components that are operated under computer control (Figure 3):

- The Robotic Arm
- The Carousel
- The Tip Stripping Arm
- The Hydraulic System

Figure 3 – RoboSep™ Instrument



With these systems acting in concert, RoboSep™ performs the following actions to automate EasySep®:

- accurately dispenses magnetic labeling reagents into the cell samples using sterile disposable 1 mL tips,
- mixes the reagents and samples using a sterile disposable 5 mL tip,
- transfers the sample to the magnet for separation using a second 5 mL tip,
- keeps track of the appropriate incubation times.

A custom-designed single-use tip rack contains the pipette tips necessary to process a single sample (Figure 4). The rack is sterilized by gamma-irradiation. Remove the cap prior to use.

Scheduling software sets the sequence in which RoboSep™ will execute all of the actions required to process up to 4 samples. This scheduler gives RoboSep™ the flexibility to perform different types of separations at the same time.

Please refer to RoboSep™ Product information sheets (PIS) for sample volumes.

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Figure 4 – Tip rack with and without protective cap and lid

1.1.3 The Robotic Arm and Carousel

The robotic arm (Figure 5) rotates and moves up and down driven by 2 independent stepper motors. The rotation of the carousel is driven by a single stepper motor. The carousel is divided into 4 quadrants (Figure 6), where a quadrant defines the minimum functional area for processing a sample. Each quadrant is designed to accommodate a 14 mL sample tube, a magnet with a 14 mL separation tube, up to 3 reagent vials, a tip rack and 2 multifunctional 50 mL tubes.

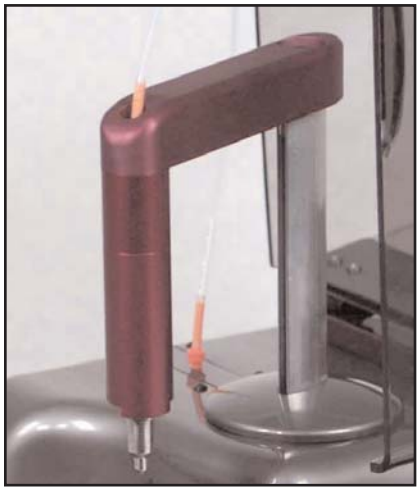

Figure 5 – The Robotic Arm is capable of vertical and rotational motion. The stainless steel tip head at the end of the arm is used to pick up pipette tips.

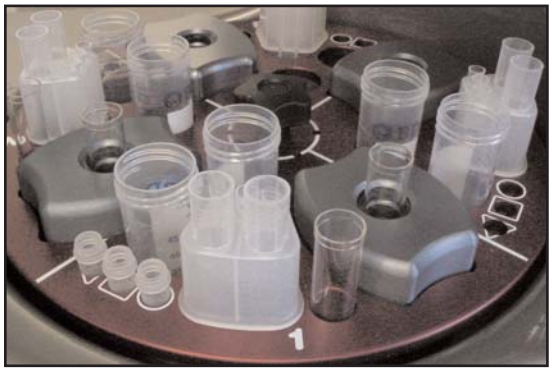

Figure 6 –The Carousel is divided into quadrants. The quadrant shown here is fully loaded with the magnet, tip rack, reagent vials and tubes required to carry out a separation.

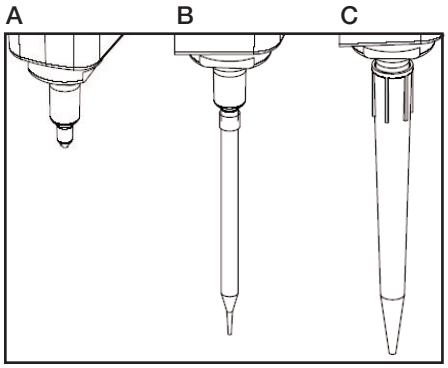

Figure 7 – The tip head (A) has two conical surfaces that engage with the 1 mL (B) and 5 mL (C) sterile disposable pipette tips.

By coordinating the rotational and vertical movement of the arm with the rotation of the carousel, RoboSep™ picks up sterile disposable tips from the custom tip racks on the carousel and then uses them to transfer fluids from one container to another or to mix the fluids in a given tube.

The robotic arm can pick up both 1 mL and 5 mL sterile disposable pipette tips using a unique tip head that has two conical tip sealing surfaces (Figure 7). This dual tip capability is required so that RoboSep™ can accurately dispense volumes from 12.5 µL up to 10 mL. RoboSep™ uses 1 mL tips to aspirate and dispense the magnetic labeling reagents and 5 mL tips to transport the sample and buffers.

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1.1.4 The Tip Stripping Arm

RoboSep™ replaces the disposable tips in the tip rack after each use. This strategy eliminates the need for a waste tip area on the instrument and facilitates clean-up after a run, by simply disposing of the tip box appropriately. Figure 8 shows how the pipette tips are removed: the robotic arm positions the tips in the tip rack, the tip stripping arm swings out to engage the tip head just above the pipette tip and then the robotic arm moves upward, stripping the tip off the tip head. The two different sized slots on the tip stripping arm engage the different sized pipette tips.

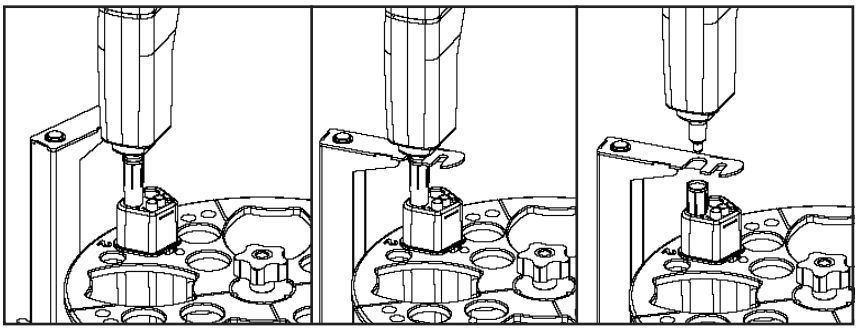

Figure 8 – Disposable 5 mL tip being replaced in the tip rack. The robotic arm places the tip partway into the rack (A). The tip stripping arm swings out to engage the tip head just above the tip (B). The robotic arm then moves up and the tip falls into the tip rack (C).

1.1.5 The Hydraulic System

The hydraulic system is comprised simply of a positive displacement piston pump connected to a deionized water bottle on one side and to the pipette handling tip head on the other. The only visible parts of this system are the water bottle and the tubing running from the console to the robotic arm. The positive displacement piston pump does not require any user maintenance because the piston seal has a substantially longer operating life than the seals on syringe pumps used in other instruments. In addition, because the hydraulic fluid does not contact the samples or reagents, RoboSep™ uses deionized water which is less damaging to the piston seal. The use of water instead of air as a hydraulic fluid allows a high degree of accuracy and high-speed dispensing. The water effectively acts as an incompressible extension of the pump piston, and therefore the hydraulic system operates with a dead air volume similar to that in a manual pipettor.

1.1.6 Homing the Carousel and Robotic Arm

RoboSep™ tracks the position of the robotic arm and carousel relative to physical markers called homing flags. A home position is registered by the computer when a homing flag trips an optical sensor. The carousel homing flag is readily visible as a projection on the bottom plate. This projection trips an optical sensor which can be seen on the front inside wall of the bowl when the carousel is removed. The robotic arm homing flags and sensors are not visible. Homing of the carousel and robotic arm is performed automatically at start-up, at the beginning of each cell separation experiment and after the instrument has been paused during a run. The robotic arm home positions are detected again periodically throughout a run.

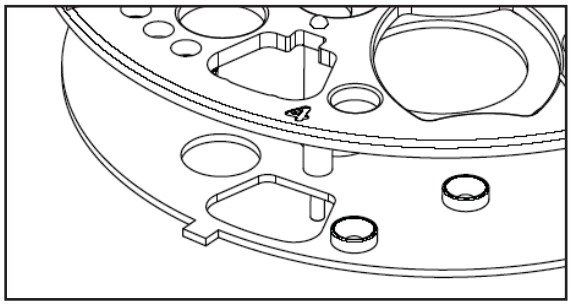

Figure 9 – The carousel home flag is visible as a projection from the bottom plate in this schematic diagram.

To ensure correct operation of the instrument, it is essential that no mobile part be moved or touched during a run.

Homing is the only mechanism by which RoboSep™ determines where all the items on the carousel are, and so any disruption of the carousel or the arm while they are in operation will likely cause pipetting actions to fail. This is why RoboSep™ operates with a transparent lid over the arm and carousel. If the lid is opened during an experiment, the instrument will finish the current action and then pause. RoboSep™ will automatically execute a homing sequence once the lid is closed and the run is resumed.

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1.2 Instrument Set-Up

1.2.1 Unpacking the Instrument

A StemCell Technologies Inc authorized agent will be present to help you unpack and install the instrument.

1.2.2 Instrument Placement

To ensure adequate cooling of RoboSep™, place it on a clean, flat surface, and be sure that there is at least a 10 cm (4 inches) clearance around each side of the instrument. Make sure that the bench space is free of any foreign objects or debris that could block the fan vents. RoboSep™ is designed to fit in most biocontainment hoods for sterile operation. RoboSep™ is not specified for use in a cold room (4ºC, 39ºF).

1.2.3 Power and Data Connections

Figure 10 - Power and data connections, hydraulic fluid bottle

Connect the power cord provided with RoboSep™ to the power supply outlet located at the bottom right side of the instrument, next to the fuse box and the power switch (Figure 10). Connect the other extremity of the power cord to a 3-prong, grounded AC outlet rated 4A, 110–240 V. Do not use an adapter to a two-terminal outlet.

Data connections to RoboSep™ are through an Ethernet port and 2 USB ports. Chapter 4 provides more detailed instructions on setting up RoboSep™ on a network or for connection to a laptop via cross-over cable.

1.2.4 Powering Up and Shutting Down

Make sure the instrument is set up in an adequate location and is connected to a power source, as described in sections 1.2.2 (Instrument Placement) and 1.2.3 (Power and Data Connections).

Power up RoboSep™ by activating the switch located at the bottom right side of the instrument (Figure 10). RoboSep™ first loads the computer operating system and then the instrument control software and user interface. The touch screen provides visual confirmation that these processes are occurring. After a short period of time, the robotic arm and carousel will move. The start-up sequence is complete once the start screen is visible (see Figure 11).

To shut down RoboSep™, go to the “Instrument Tasks” section of the graphical user interface by pressing the appropriate tab at the top of the touch screen. Press “Basic Shutdown Protocol”. Wait until the screen becomes black, and then turn off the power switch.

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1.2.5 Priming the System

RoboSep™ performs a priming sequence at the beginning of every cell separation protocol to minimize the effect of air bubbles that naturally accumulate in the hydraulic system. However, when RoboSep™ is used for the first time, or if the hydraulic fluid bottle has run dry, it is necessary to run a separate priming protocol.

1. Fill the hydraulic fluid bottle with 250 mL of deionized water and connect the bottle to the hydraulic system tubing in the compartment located at the right of the instrument (Figure 10).
2. If it is turned off, switch the instrument on and wait until the end of the start-up sequence.
3. Press the “Instrument Tasks” tab, select “Basic Prime” under the “Maintenance” tab and then press the green “Load” button.
4. Place a 50 mL tube in the appropriate slot of the carousel as indicated on the screen.
5. Press “Run”.

Repeat the priming sequence if no water has been expelled from the tip head into the waste tube by the end of the priming sequence. Once priming is complete the waste tube can be emptied.

1.3 Running RoboSep™: Quick Start Instructions

Note: Before using RoboSep™, always ensure that the hydraulic fluid bottle contains enough deionized water for the planned experiments.

1. Power up RoboSep™ and wait for initialization to complete.
2. Follow the instructions on the message bar at the top of the screen. Press “Select Protocol” to bring up the list of available protocols. Choose the desired protocol from the list and then enter the sample volume. Repeat this process until all the desired protocols (up to 4) are selected.
3. Press “Load” to begin the loading sequence. Lift the lid and load the indicated carousel quadrant(s) with the items listed on the left of the screen. Press “Loaded” once each quadrant is ready. When all quadrants are loaded, close the lid.
4. Press “Run”. RoboSep™ will now complete the selected protocols unless it is paused or halted. The time remaining until completion is displayed on the screen.
5. Once the run is complete, press “Unload”, open the lid and collect the cells of interest. For positive selections the cells of interest are in the magnet tube. For negative selection the cells of interest are in the 14 mL sample tube of the second quadrant (standard 2 quadrant negative selection), or the 50 mL negative fraction tube of the first quadrant (1 quadrant negative selection).
6. Unload the rest of the carousel and store the reagents appropriately. Discard the tip boxes containing the used tips in the appropriate waste container.
7. The instrument is now ready for another run. If no more runs are planned for the day, or if a spill occurred, clean the instrument as detailed in Chapter 5. To conserve energy, turn off the instrument at the end of the work day.

Note: RoboSep™ protocols may differ from the standard manual separation protocols because they have been optimized for an automated system. Unless otherwise noted all RoboSep™ procedures have been optimized for use at room temperature, regardless of the temperature recommended for the manual procedure.

2. Running RoboSep™: Detailed Instructions

2.1 Introduction

Power up the instrument as indicated in Chapter 1.2.4 “Powering Up and Shutting Down”. The Robosep™ graphical user interface will load automatically. Wait for the end of the start-up sequence before touching the touch screen, the lid, or other moving parts of the instrument. Start-up is complete when the “Sample Processing” screen appears on the user interface screen, as shown in Figure 11 - Start screen.

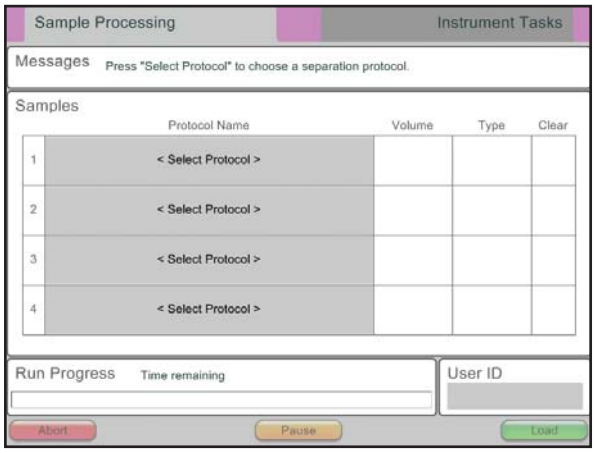

Figure 11 - Start screen

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The user interface consists of 2 main sections defined by tabs at the top of the screen: the “Sample Processing” section that is visible at start up and the “Instrument Tasks” section (Figure 11). The light grey tab indicates which section is currently active. You can switch from one section to the other at any time by touching the appropriate tab. The various functions accessible in these 2 sections are detailed in the following chapter.

2.2 Setting Up a Run

Go to the “Sample Processing” section of the user interface. The sample processing screen is initially divided into 5 areas: Messages, Samples, Run Progress, User ID and a row of action buttons along the bottom.

The Messages area indicates what step is next in the set-up process to start running RoboSep™. The Samples area is divided into 4 rows corresponding to the 4 quadrants on the carousel. Each row has columns to display the protocol name, the sample volume (mL), and the type of cell selection (positive or negative). Once protocols have been selected, this area indicates on which quadrant of the carousel each protocol will be run (Figure 12). The Run Progress area has a progress bar and count-down clock that show the time to completion of the run (Figure 15). The USER ID area allows the user to enter their unique code for reporting purposes (see Table 1, Section 2.4). The action buttons are Abort, Pause and Load.

2.2.1 Entering a User ID

To enter a user ID:

1. Press the grey box under the “User ID” heading. A numeric pad will pop up.
2. Key in the user ID, and press the “Enter” key.

A user ID can be input at any point before a run begins. The User ID information is stored internally and is included in the report file that is generated upon completion of each run (see Table 1, Section 2.4). User ID helps to keep track of usage in a multi-user environment .

2.2.2 Selecting Protocols

To select a protocol:

1. Touch “Select Protocol” in any row of the Samples area. A list of the available protocols appears on the screen (Figure 12).
2. Select a protocol by touching the protocol name. A numeric pad pops up (Figure 13).
3. Key in the sample volume in mL, and press the “Enter” key. The original “Sample Processing” screen will re-appear with the selected protocol in the appropriate quadrant row.

Review the information. To remove the protocol, press the “X” in the last column. To change the protocol, press the protocol name and repeat the protocol selection process above. To change the sample volume while keeping the same protocol selected, press the sample volume for this protocol, and enter a new volume.

Repeat the protocol selection process until all the desired protocols are entered. Up to 4 different protocols can be chosen. When a negative selection protocol with 2 rounds of separation is selected, the interface automatically assigns 2 consecutive quadrants for the protocol. Once 3 quadrants are occupied, only protocols using 1 quadrant will be displayed.

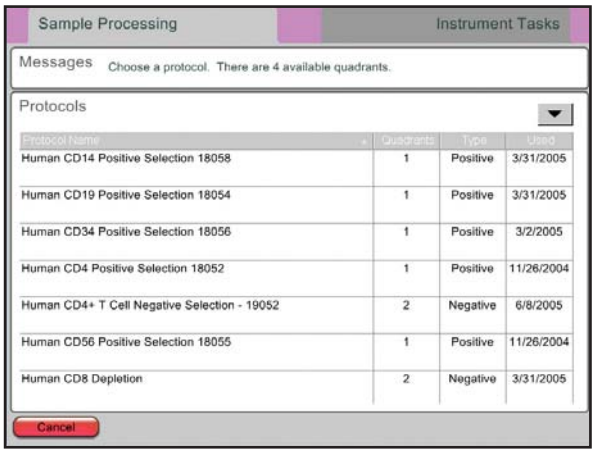

Figure 12 - Select a protocol from list

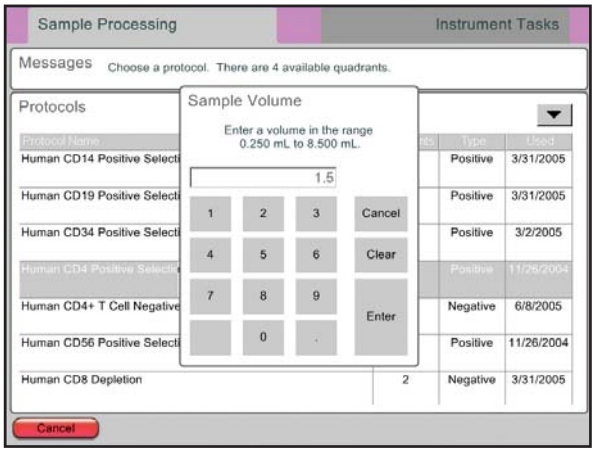

Figure 13 - Entering sample volumes

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Protocol Order

The protocols are listed in order of last use, with the most recently used protocols at the top of the list (Figure 12). The protocols can also be sorted by name or type. To change the basis of sorting, touch the appropriate column heading. For example, to sort protocols in alphabetical order press the Protocol Name heading. An arrow in the heading indicates if the list is sorted in ascending or descending order. The user can move up and down the list by using the arrows at the top right corner of the protocols window.

2.2.3 Loading the Carousel

Once all the desired protocols have been selected, you are ready to begin loading the carousel.

1. Press the start button. An image of the carousel appears (Figure 14). The active quadrant number(s) is displayed at the bottom right of the window. At the top center of the window, the name of the protocol assigned to this quadrant is also displayed.

2. Identify the necessary reagents and resources required for the separation. On the left hand side of the window is a list of all the reagents and resources that need to be loaded for the current separation. The selected separation protocol is listed just above the carousel and the quadrant number(s) for the protocol are listed along the bottom of the screen. The user can move up and down the list by pressing the arrows located at the top and bottom of the list. Lot numbers and sample IDs can be entered by first touching the item on the list and then the grey box under the Reagent Lot ID heading (see below for further details).

3. Load the reagents and resources. The reagents and resources list starts with items near the center of the carousel and ends with items near the rim to facilitate aseptic loading. Touch the first item on the list. This highlights that item in green and indicates the location of the item on the carousel with a green circle. Turn the carousel so that the indicated quadrant is in a convenient position and place the item in the indicated location. Continue down the list loading each item in a similar manner.

4. Before placing the tip rack in the carousel, remove the plastic collar and then the top cap (Figure 4). Ensure that the case does not open when removing the top cap. Place the rack on the carousel and push down to fully seat the rack (this ensures that the tips are in the correct location for pick-up by the robotic arm).

5. Loading Reagents: The minimum reagent volumes required for the given cell separation procedure are displayed below the names of the required reagents. Verify that your vial has that minimum required volume. To assist in proper placement, the reagent vial labels have symbols that correspond to symbols on the carousel and on the touch screen. Please note that the EasySep® magnetic particle vial size for RoboSep™ has increased to 1.5 mL. Use of the 0.5 mL EasySep® vial may cause the RoboSep™ pipette tip to jam.

6. Press the green “Loaded” button when all the reagents and resources are loaded on the active quadrant(s).
   The reagents and resources required for the next selected protocol will appear.

7. Repeat steps 2-6 until all the required quadrants are loaded. Close the instrument lid.

8. Press the green “Run” (Figure 14) button to start the cell separation experiment. A warning message appears, asking the user to verify that all the reagents and resources are correctly loaded and that nothing can interfere with the movements of the instrument. Please ensure that the lids have been removed from all vials and resources, especially the buffer bottle. If everything is clear, press “Confirm”.

9. Observe that the initial prime step ejects water from the tip head into the waste tube in carousel quadrant 1. This ensures that the hydraulic fluid system is properly connected.

   The experiment is now in progress. The time remaining until completion is displayed at the bottom of the screen (Figure 15).

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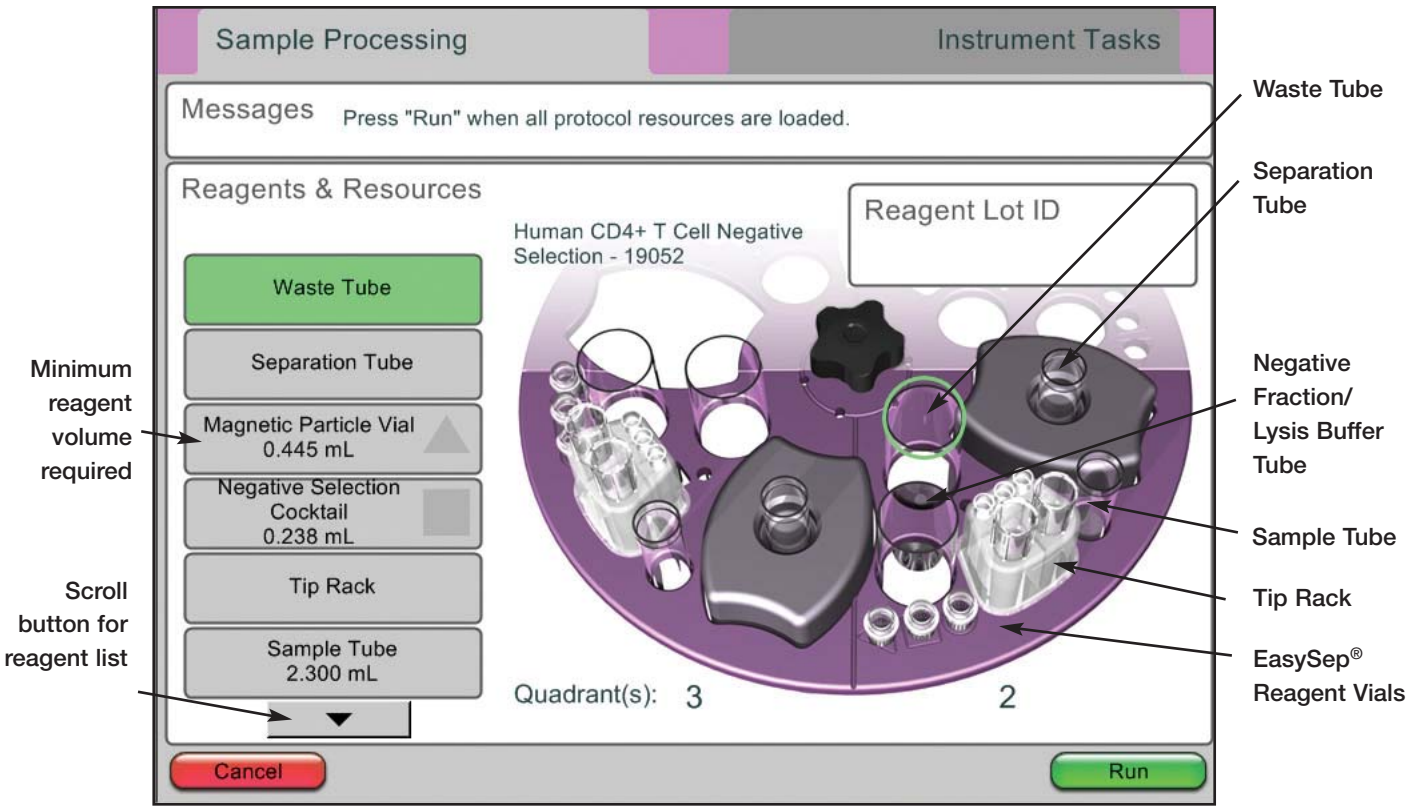

Figure 14 - Carousel layout. The locations of the items listed along the left hand side of the screen are indicated with a green circle when the listed item is selected. In this example the waste tube is highlighted on the left and indicated with a green circle in quadrant 2.

Reagents and Resources

The sample tube and separation tube are 14 mL round-bottom tubes (e.g. Falcon 2057). The waste tube and negative fraction tube/lysis buffer tube are 50 mL conical bottom tubes (e.g. Falcon 2070).

The Service Rack is provided to hold the reagents and sample prior to loading them on the carousel and to keep track of the caps during a run (Figure 16). The rack is laid out in quadrants like the carousel, with symbols on the reagent storage locations to assist with keeping track of the correct caps.

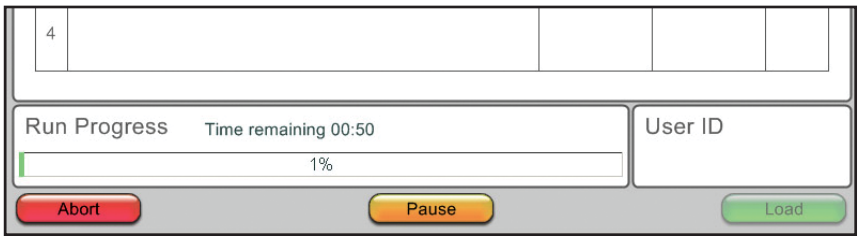

Figure 15 - Run Progress. Once a run has begun, progress is shown at the bottom left, with an indication of how much time remains.

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Sample ID and Lot numbers

Sample ID and reagent lot numbers can be entered during the loading sequence for each protocol.

1. Select the sample or reagent by touching the button in the list on the left of the screen.
2. Touch the grey box under the Reagent Lot ID heading in the upper right corner of the screen. This brings up a numeric key pad.
3. For reagents, enter the last 5 digits of the reagent lot number; for sample ID, up to 48 digits can be entered.

(**Note:** Although EasySep® reagent lot numbers are formatted 88A88888, only the last 5 digits are required to uniquely identify the lot.)

Figure 16 - The Service Rack is divided into quadrants like the carousel.

Collect the cells at the end of the experiment

Press "Unload" and allow 5 seconds for the robot and carousel to move to a safe position. Open the instrument lid.

Collect the cells of interest:

- **Positive selection:**
  - o Remove the 14 mL tube containing the isolated cells from the magnet (Figure 17, A).
  - o If desired, collect the 50 mL tube containing the depleted fraction located at the left of the tip box.

- **Negative selection:**
  - o If two rounds of separation were performed, collect the enriched cells in the 14 mL tube located at the left of the magnet on the second quadrant used for the negative selection procedure (Figure 17, B).
  - o If one single round of separation was performed, collect the 50 mL tube containing the enriched cells located at the left of the tip box (Figure 17, C).
  - o If desired, collect the 14 mL tube(s) containing the labeled cells located in the magnet(s). Unload the carousel and store the reagents appropriately. Discard the tip boxes containing the used tips in the appropriate waste container. Check that the hydraulic fluid bottle contains enough deionized water for further experiments.

The instrument is now ready for another experiment.

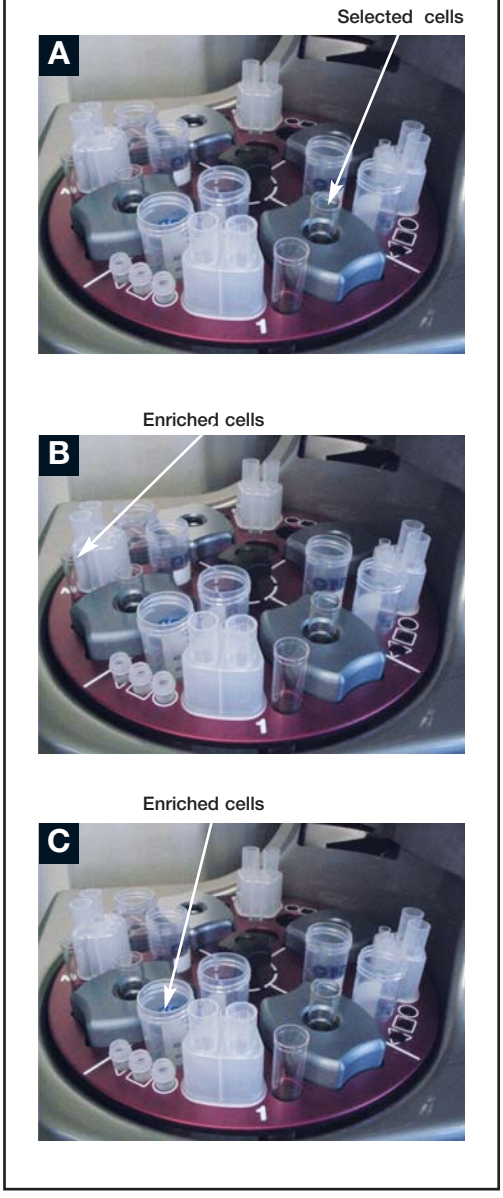

Figure 17 - Location of desired cells after separation:

A: Positive selection
B: Negative selection, 2 rounds
C: Negative selection, 1 round

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2.2.4 Removing the Carousel

The carousel can be easily removed from the instrument for cleaning or to facilitate loading and unloading of the samples and reagents. Some users may prefer to remove the magnets from the carousel prior to removing the carousel, as the magnets are relatively heavy.

To remove the carousel:

1. Rotate the black central knob (Figure 18) counterclockwise until the threads have disengaged.

To replace the carousel within the instrument:

1. Place the carousel over the bearing hub.
2. Align the holes around the knob with the pins on the bearing hub by slowly rotating the carousel.
3. Screw the central handle clockwise until locked. It is important to tighten the knob fully so that the carousel stays level when the robotic arm pushes down on it to pick up pipette tips.

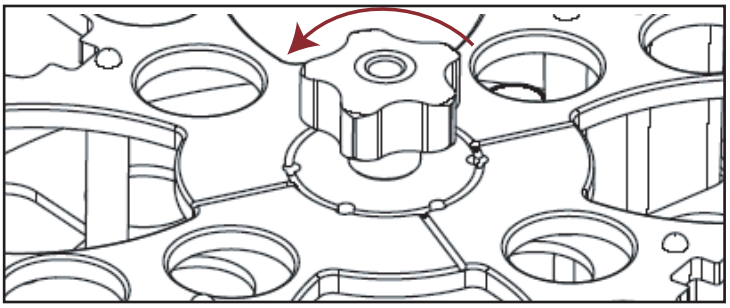

Figure 18 - Close-up of knob that fastens the carousel to the bearing hub.

2.2.5 Preparing Cells

Refer to the product information sheet that comes with your EasySep® reagents for instructions on how to prepare cells for separation using RoboSep™. It is important to use the recommended cell concentration for best results. Initial cell suspension volume should be between 250 µL and 8.5 mL. Ideally the sample should be a single cell suspension. However, RoboSep™ tips will not clog if small aggregates are present.

2.2.6 Pause and Abort Buttons

Hitting the Pause button will cause RoboSep™ to interrupt the run as soon as it completes the current action. Pressing the Resume button will restart the run at the next scheduled action after RoboSep™ orients itself by performing homing actions. The Abort button also stops execution of the run as soon as the current action is complete, but with the option to exit from the protocol completely or to resume execution.

2.3 Instrument Care and Shutdown

If no more experiments are to be performed on that day, or if there was a spill on the instrument, clean the instrument as detailed in the “Care and Maintenance” section (Chapter 5).
To conserve energy, turn off the instrument at the end of the work day.

- Navigate to the “Instrument Tasks” section of the graphical user interface (Figure 19);
- Select “Basic Shutdown Protocol”;
- Wait until the screen becomes black, and then turn the switch on the right side of the instrument to the off position.

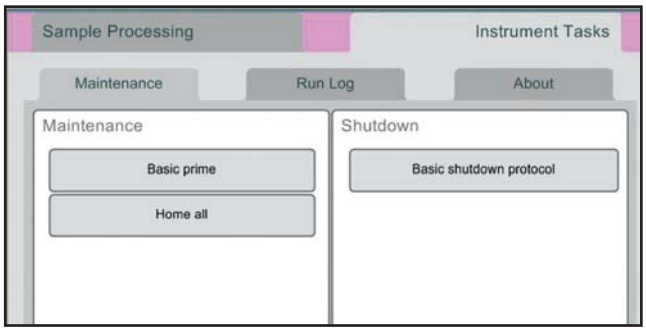

Figure 19 - The shutdown protocol is located under Maintenance on the Instrument Tasks tab

2.3.1 Aseptic Operation of RoboSep™

To ensure aseptic operation, RoboSep™ must be used in a biocontainment hood. RoboSep™ is designed to fit easily in most commercially available hoods. In addition, RoboSep™ does not affect sterility within the biocontainment hood. This has been verified by particle count as per ISO standard 14644-1.
Although the hydraulic fluid is internal to the instrument and does not come into contact with the sample, reagents, or tips during normal operation, we recommend using sterilized water for aseptic operation.

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2.4 Reporting

Usage data is automatically saved during RoboSep™ operation. RoboSep™ has the ability to keep track of the experiments that are performed using the instrument. To benefit fully from this function it is recommended that the following information be provided at the time of the experiment:

- User ID, in the case of multiple users
- Lot number for each of the reagents used with the instrument.

Instructions on how to input this data are detailed in Chapter 2: "Running an Experiment: Detailed Instructions". One report file is generated for each day when RoboSep is active. The files can be found in the folder C:\Program Files\STI\RoboSep\reports\. Subfolders are automatically created when necessary to organize the report files by year, and then by month within the year's folders. The files are in standard text format (.txt), and are automatically named according to the following convention: "Report_DDMMMYYYY.txt". To access these files, you need to set up a connection between RoboSep™ and an external computer, as explained in Chapter 4: "Communications and File Transfer."

End of Run Report
##

Scheduled ETC:	20050613T13:29:29	
Operator ID:	53	
Actual Start:	13 Jun 2005 12:13:17	
Actual Finish:	13 Jun 2005 12:26:08	
Final Status:	COMPLETED	
Sample #1		
Sample ID:	1	
Sample Label:		
Protocol ID:	1220525925	
Protocol Label:	Mouse T Cell	Negative Selection 19751
Sample's Initial Quadrant:	1	
Sample Volume:	5.9 ml	
Quadrant #1		
Cocktail:	13569	(0.69 ml)
Particle:	13256	(0.69 ml)
Lysis:	Unlabeled	(Not Used)
Antibody:	13265	(0.395 ml)
Sample:	326698	(Not Used)
BCCM:	Unlabeled	(10.0 ml)
Waste Vial:	Needed	
Separation Vial:	Needed	
Sample Vial:	Needed	
Tip Box:	Needed	
Quadrant #2		
Cocktail:	Unlabeled	(Not Used)
Particle:	Unlabeled	(Not Used)
Lysis:	Unlabeled	(Not Used)
Antibody:	Unlabeled	(Not Used)
Waste Vial:	Not Needed	
Separation Vial:	Needed	
Sample Vial:	Needed	
Tip Box:	Not Needed	

Table 1 - Example of report file

3. RoboSep™ Protocol Editor

The RoboSep™ Protocol Editor is a stand-alone program that is installed on a personal computer. The editor is used to modify existing protocols or to write new ones to then be imported into RoboSep™.
Note: This program is not required for functionality of RoboSep™.

3.1 Installation

To install the editor, insert the CD and then double-click on "Setup For Release". The installer will open and guide the user through the installation process.

3.2 Start-Up

Launch the protocol editor from the shortcut on your desktop. If this is not visible, double-click on "ProtocolEditor.exe" in the default install location of the protocol editor of "C:\Program Files\STI\RoboSep\bin". When the protocol editor console is initially opened, all the fields are greyed-out. To begin you must select either "New" or "Open" from the "File" drop-down menu. Select "New" to begin creating a new protocol or "Open" to edit an existing protocol.

3.2.1 Editing an Existing Protocol

The quickest and most reliable way to create a protocol for a specific application is to base it on an existing protocol. To edit an existing protocol with the protocol editor, click the "Open" button in the "File" menu and select the desired protocol. This will populate the editor screen with the commands and settings for that protocol. Once the desired protocol is opened, any of its settings can be changed, commands can be added or deleted and the order of command execution can be changed. A description of the commands is found in Section 3.3: "Protocol Structure". When satisfied with the edited protocol, follow the procedure under "Saving a Protocol" to save your work.
Note: In order not to over-write the original protocol, the "Save As" option must be selected instead of "Save".

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3.2.2 Writing a New Protocol

In the “File” menu, click on “New”. The boxes in the editor screen will become active and several fields will show flashing red exclamation points (Figure 20). If you place the mouse over the flashing red points, a context-specific description will appear on the screen to assist with appropriate completion of the field.

“Move Up” & “Move Down”: Selected commands can be moved up or down to change the order in which they will be executed.

“Protocol Type”: Select the type of separation from the pull-down menu.

“Label”: Enter the name of the protocol that will appear in the “Protocol Selection” screen on RoboSep™.

“Author”: Enter the author of the protocol.

“Sample Volume”: Enter the minimum and maximum sample volumes.

“Command Sequence”: The list of programmed commands will appear here in the order in which they will be executed.

“Command Details”: Parameters that are specific to different commands can be changed here.

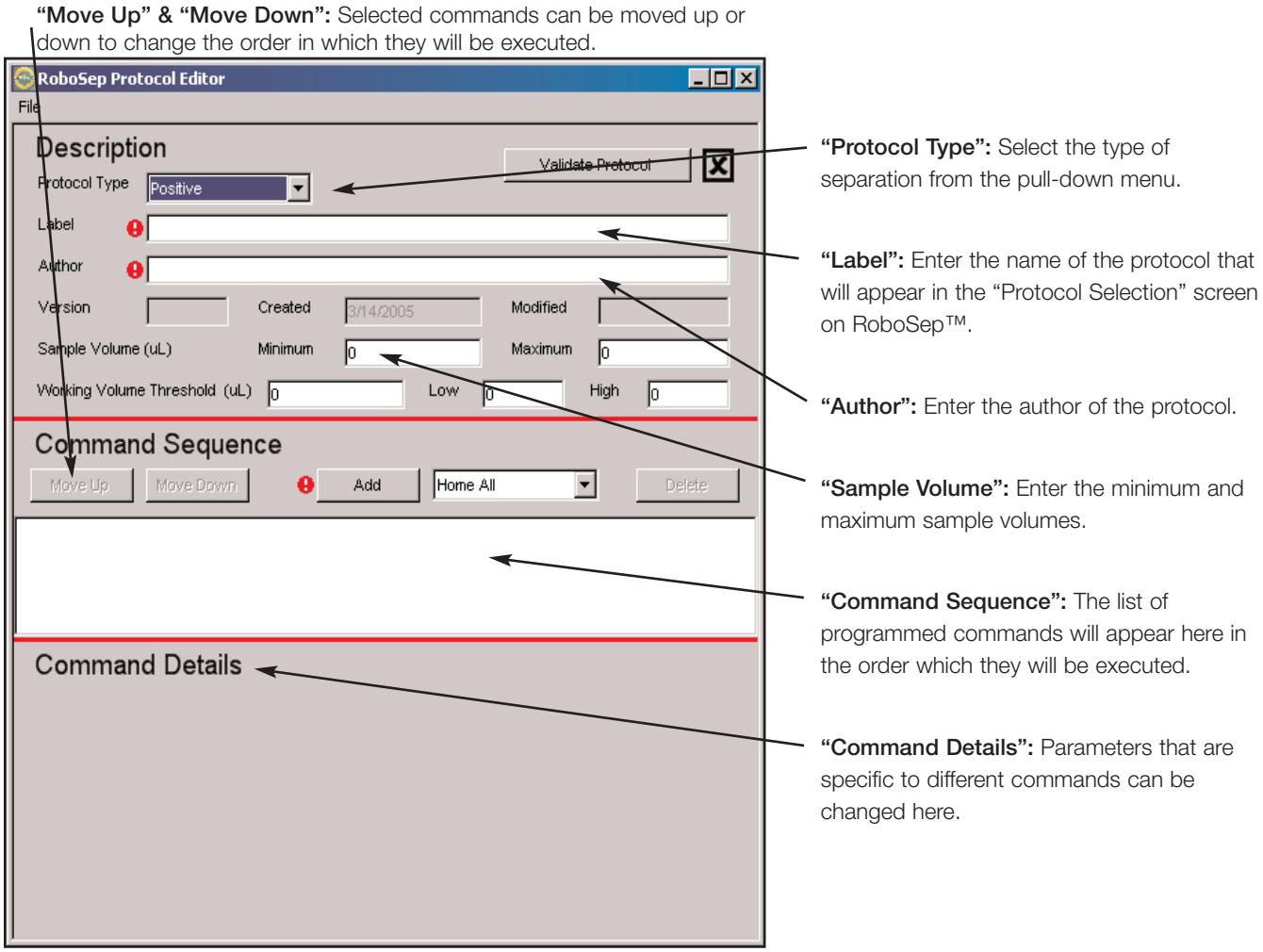

Figure 20 - The protocol editor screen fields. Required information is highlighted with an exclamation mark.

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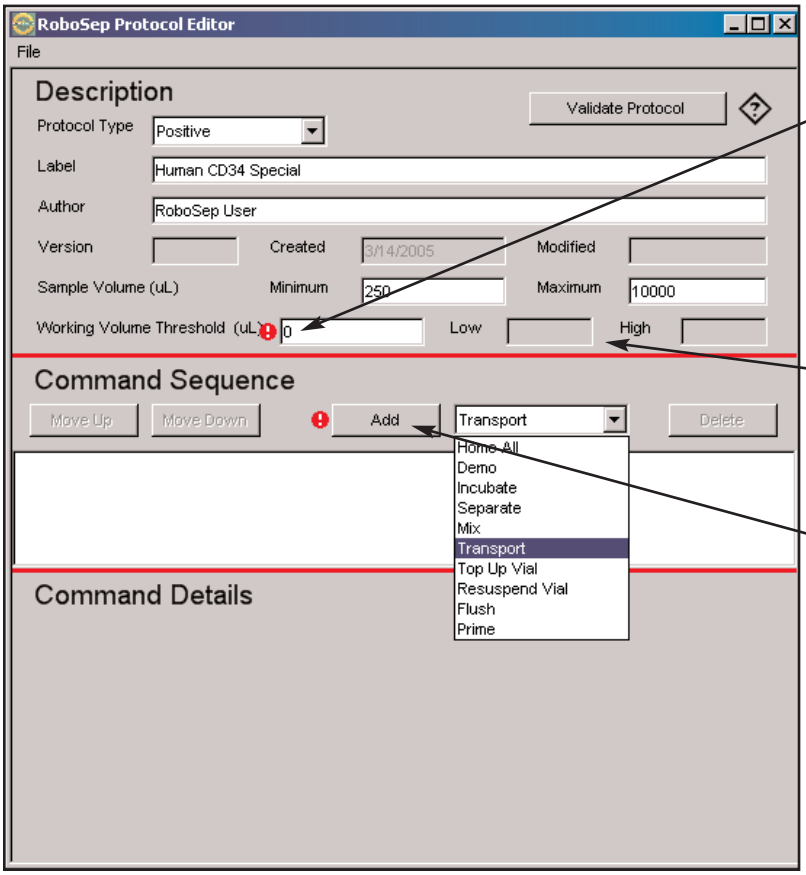

"Working Volume Threshold": Enter the sample threshold volume. RoboSep™ will use the "High" volume for top-up commands with any sample above or equal to the threshold volume. The "Low" volume will be used for top-up commands with any sample smaller than the threshold volume.

"Working Volume Low and High": Enter the lower volume and upper volume that RoboSep™ will use during top-up commands.

"Add": Use the pull-down menu to select the type of command to be added and click the "add" button.

Figure 21 - The protocol editor screen working volume threshold fields

3.3 Protocol Structure

A protocol is defined by protocol-specific fields that define global parameters for the protocol and by a list commands which are executed in sequence.

3.3.1 Protocol-Specific Fields

Protocol type

Select Positive for positive selection protocols and Negative for negative selection protocols. Maintenance and Shutdown protocols are for service and diagnostic routines and are not useful for cell separation.

Label

The name you enter here is what will appear in the protocol list. This name must be unique for it to be registered as a valid protocol.

Author, Version, Created and Modified

These fields allow you to keep track of the history of a protocol that undergoes modification.

Sample Volume Mininum and Maximum

These fields define the allowable range of sample volumes.

Minimum should be set such that all "relative volume" dispensing actions are of at least 12.5 µL. For example, if particles are added at 50 µL/mL of cells then the minimum sample volume should be 250 µL (50 µL/mL x 250 µL ÷ 1000 µL/mL=12.5 µL).

Maximum should be set such that the total sample volume after all reagent additions is less than 10 mL. For example, if cocktail is added at 100 µL/mL and particles at 50 µL/mL of cells, then the maximum sample volume should be set at 8.5 mL (8.5 mL + 0.1 x 8.5 + 0.05 x 8.5 = 9.8 mL).

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Working Volume Threshold, Low and High

After the magnetic labeling steps, RoboSep™ tops up the sample to a given working volume before transferring the sample to the magnet for separation. The top-up volume can be set such that sample volumes less than a given "Working Volume Threshold" are topped-up to a "Low" working volume while sample volumes greater than or equal to the threshold are topped-up to the "High" working volume. This capability exists to improve separation performance for small volume samples.

Suggested settings for negative selection protocols are "Working Volume Threshold" = 4000 µL, "Low"= 5000 µL, "High" = 10000 µL

Suggested settings for positive selection protocols are "Working Volume Threshold" = between 1500 and 2000 µL, "Low"= 2500 µL, "High" = 10000 µL.

3.3.2 Protocol Command-Specific Fields

There are a limited number of commands used to automate cell separation processes on RoboSep™. These commands are Transport, Mix, Incubate, Top-up and Separate. To add a command:

1. Select a command from the pull-down menu in the "Command Sequence" section and click "Add".
2. Enter the appropriate parameters (see below).
3. Click on the white area in the "Command Sequence" section to confirm the settings.

Each command has specific parameters that influence how it is executed. These will appear in the "Command Details" section of the editor console. All commands have a **"Label"** parameter and an **"Extension Time"** parameter. The Transport, Mix and Top-up commands have **"Source"** and **"Destination"** parameters. The Transport and Top-up commands have the **"Free-air Dispense"** and **"Volume"** parameters. The Incubate and Separate commands are identical and have the **"Incubation Time"** parameter.

"Label": The description in this box will appear in the "Command Sequence" list once all the details of the command have been entered.

"Extension time": Each command takes a set amount of time to execute. The extension time specifies what additional time is available to RoboSep™ to facilitate the scheduling of all the required actions.

"Source": This is the container (tube or reagent vial) from which the pipette will aspirate. If a reagent vial is specified as the source, a 1 mL pipette tip is used automatically. If a sample tube or magnet tube is the source, then the 5 mL tip reserved for cell handling is used. If the source is the buffer bottle or lysis buffer tube (negative fraction tube) then the 5 mL tip reserved for buffer handling is used. The source is chosen from a pull-down list which is sorted by relative quadrant number. The source tube should be in "Q1" in most cases, since "Q1" is the start quadrant for all protocols. This means that a protocol loaded in quadrant 2 will start in quadrant 2.

"Destination": This is the container into which the pipette will dispense. The destination container is also selected via a pull-down menu. The list is sorted by relative quadrant number. A protocol with a source in Q1 and a destination in Q2 will occupy 2 quadrants on the carousel. If the protocol is loaded in quadrant 3, the destination will be in quadrant 4.

"Free-air Dispense": When this check box is enabled, RoboSep™ dispenses the fluid that it is transporting just below the upper lip of the destination container and above the liquid in the container. This option is useful where contact with the contents of the destination tube is undesirable (e.g. preventing contamination of the buffer tip when adding buffer to the sample tube.).
Note: This option is not recommended for transfer of small volumes (e.g. addition of reagents).

"Volume": For Transport commands, the user can specify whether RoboSep™ is to transport an absolute volume in µL or a volume relative to the initial sample volume. (e.g. To have RoboSep™ add 100 µL of reagent per mL of sample volume, program the addition of a relative volume with a proportion of 0.10.). This parameter is not enabled for Top-up commands since the top-up volume is dictated by the sample working volume.

"Incubate": This parameter specifies the length of time in seconds for reagent and magnetic separation incubations.

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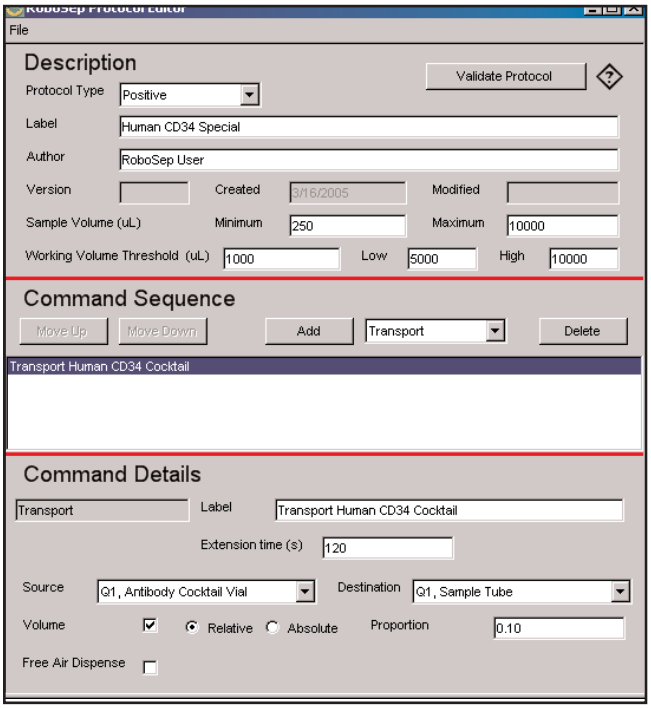


Figure 22 - Protocol Editor Screen with a new protocol open. The first transport command has been entered.

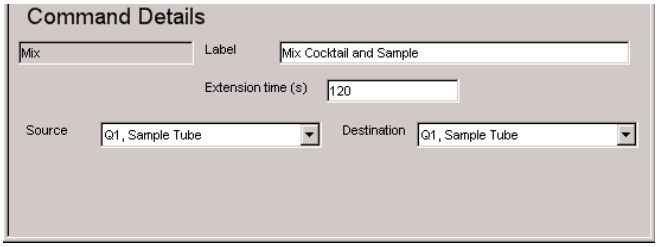
"Transport"

This command is used for transporting fluid from one location on the carousel to another and is used in most protocols to specify the amount of reagent to add to the sample, and to specify the volume of sample to move from one tube to another.

Typically, reagent volume addition is relative to the sample volume. For transporting the sample from the sample tube to the separation tube, specify the maximum volume and RoboSep™ automatically adjusts to transfer the whole amount.

"Mix"

This command is used to mix the contents of a tube. This command uses 5 mL pipette tips and therefore should only be executed where the contents to be mixed are in a 14 mL or 50 mL tube. The source and destination tubes should be the same. There are no other parameters to specify since the mixing regime is preset as a function of the volume present in the tube.



"Incubate"

This command is used to set incubation times for reagents. The incubation time is the minimum amount of time before the next command in the sequence is executed. Typical values for incubation time are between 600 and 900 seconds (10 and 15 min). For extension time a minimum of 215 seconds is recommended.

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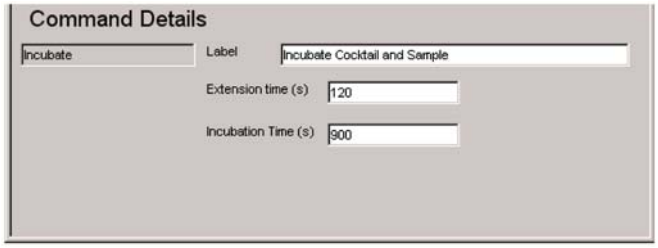
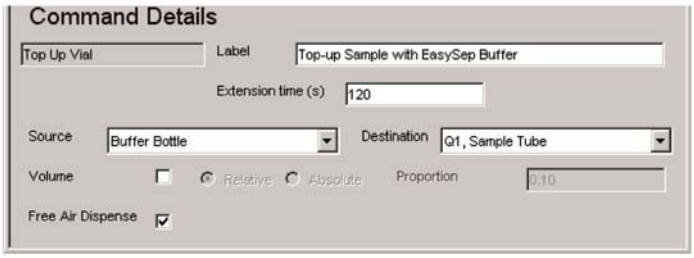


"Separate"

This command is functionally the same as the "Incubate" command and is used to set incubation times for magnetic separations. The incubation time is the minimum amount of time before the next command in the sequence is executed. Typical values for incubation time are between 600 and 900 seconds (10 and 15 min). For extension time, a minimum of 215 seconds is recommended.

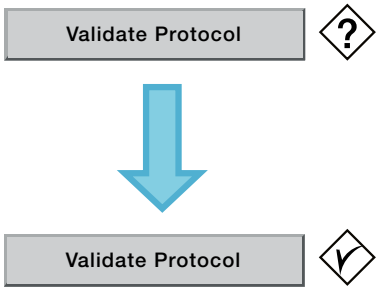
"Top-Up Vial"

This command is used to top-up a tube with EasySep® Buffer before transferring the sample to the magnet for separation, or after the supernatant has been removed following incubation in the magnet. The main difference between a "Top-Up Vial" command and a "Transport" command is that one uses the buffer tip whereas the other uses the cell tip. Although the volume parameter appears to be available, the "Top-Up Vial" command uses the specified sample volume-dependent working volumes for the protocol.



3.4 Saving a Protocol

The "Save" option will not be available until the protocol is validated by the editor. To do this, click the "Validate Protocol" button located at the top-right corner of the editor console. If successful, the symbol beside the "Validate Protocol" button will turn from a question mark to a check mark.



The editor will only ensure that all information that is critical for protocol execution is present. It does not ensure that your protocol is correctly programmed. For example, if a "mix" command is programmed for a reagent vial, the 5 mL pipette tip will collide with the top of the reagent vial and will most likely cause an error during the run. The validation process would not have warned the user of the event.

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3.5 Transferring protocols onto a USB key

1. Insert your USB key into the USB port on your PC. Your PC will “detect” the USB key as a drive/storage device.
2. Copy the RoboSep™ protocol(s) onto the key by either “copying and pasting” or by simply “dragging and dropping” the protocol.
3. Remove your USB key from the USB port.

3.6 Importing protocols from a USB key onto RoboSep™

1. To get to the desktop from within the user-interface, connect a mouse and keyboard to the USB ports (on the right side of RoboSep™) and press the Windows button located between “Ctrl” and “Alt”. This should give you access to the Windows taskbar where you can exit of the user interface by closing the DOS window.
2. Open the “RoboSep™” folder by double-clicking the “Shortcut to RoboSep™” icon on the desktop. If the “Shortcut to RoboSep™” icon is not present on the desktop, use the path “C:\program files\STI\RoboSep™” after double clicking “My Computer”.
3. Next, double-click on the “protocols” folder.
4. Insert your USB memory key into either one of the USB ports on RoboSep™. (If you have both a mouse and keyboard plugged into RoboSep™ at this time, it is recommended that the USB memory key be inserted in place of the keyboard – the mouse will be needed to drag and drop the protocols.)
5. Copy the protocol from your USB key into the “protocols” folder by either “copying and pasting” or by simply “dragging and dropping”.
6. Close all windows.
7. Double-click on the “Start RoboSep” icon on the desktop to re-open the user-interface.

Note: It is possible to import protocols without exiting the user-interface. However, the imported protocol will not appear in the “Select protocol” list until the user-interface is re-started.

4. Communications and File Transfer

RoboSep™ runs on Window XP and as such has many possibilities for communication with other computers. RoboSep™ comes configured for communication with your laptop via a cross-over cable (supplied), but can be configured to be connected to your network

4.1 Connecting to RoboSep™

For network access to shared folders, login as “guest” on the RoboSep™ machine.

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4.1.1 Set-Up for Cross-Over Cable Connection

To configure your laptop, go to the Change the Local Area Connection Properties Table by selecting “Network Connections” in the Control Panel. Select “Internet Protocol (TCP/IP)” and hit the “Properties” button to bring up the properties screen (Figure 23).

1. Select “Use the following IP address”
2. Set IP address to: 192.168.1.201
3. Set Subnet Mask to: 255.255.255.0

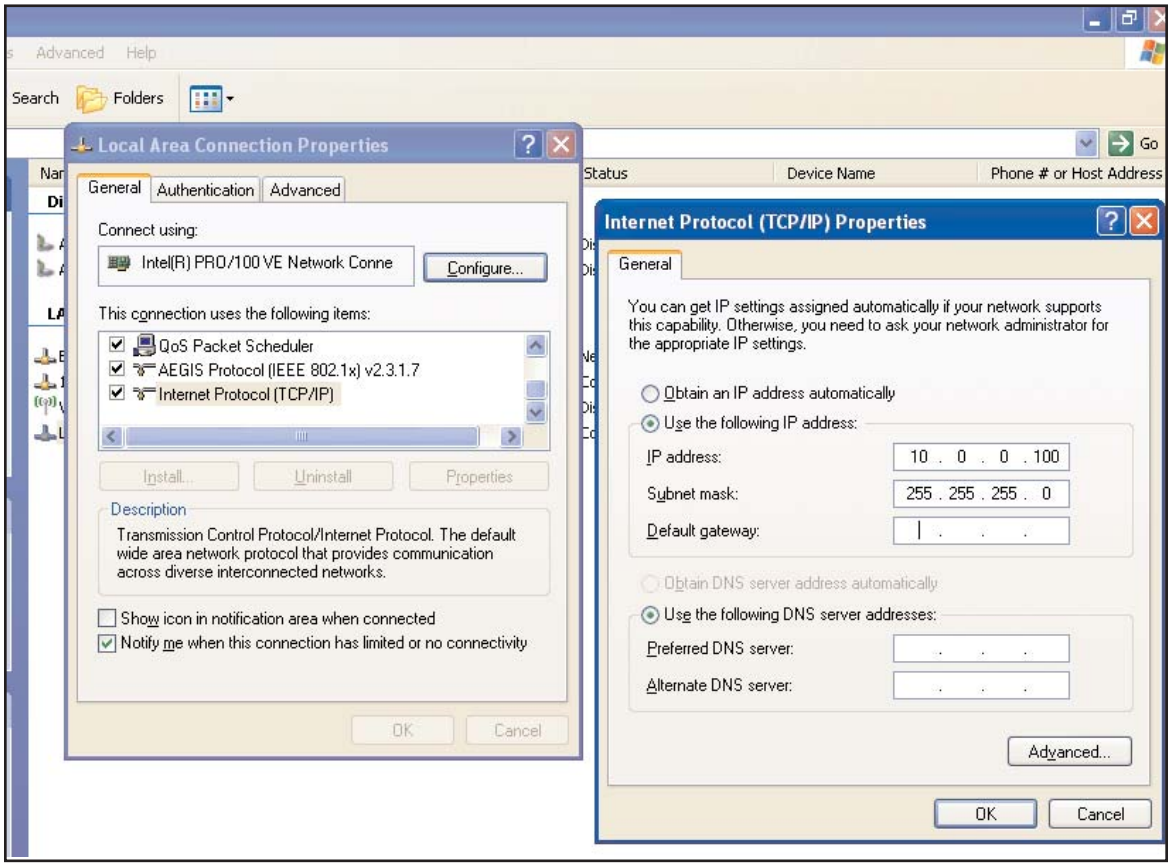

Figure 23 - Setting up your laptop to communicate with RoboSep™

4.1.2 Set-Up for Network Connection

When we install your instrument, RoboSep™ can be set up to automatically obtain an IP address from your network. This will allow you to see shared folders on RoboSep™ from any other computer on the local network. You may need to speak to your network administrator to see if this is permitted.

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4.1.3 Finding RoboSep™ on the Network

Whether you are connected to a local network or to your laptop, you will need to find RoboSep™ before you can access the shared folders. If using Windows XP:

1. Select “Search” from the Start Menu
2. Select “Printers, computers, or people”
3. Select “Computer” on network
4. Enter RoboSep™ name Robo-XXXX where XXXX is the instrument serial number listed on the back of the instrument or in the About tab of the user interface.
5. Double click on the Robo-XXXX icon. You should now see the shared folders on RoboSep™. The shared folders are: Protocols, Reports and Logs.

4.2 Adding Protocols

RoboSep™ comes with pre-installed protocols that have been optimized for cell separation from normal samples using supported EasySep® products. Protocols that you have created for other applications using the protocol editor (see Chapter 3) must be copied into the Protocols folder on RoboSep™. Once you have found RoboSep™ on the network:

1. Copy the RoboSep™ protocol(s) from your computer onto RoboSep™ by either “copying and pasting” or by simply “dragging and dropping” the protocol file into the Protocol Folder.
   Note: The file must have a unique name to avoid potentially overwriting existing protocols. To secure the protocol against accidental modification, change the file properties to “read-only”
2. Once you have transferred protocols to RoboSep™, shut down the instrument completely and then restart. This is necessary for RoboSep™ to register the new file in the protocol list.
3. Verify that the protocol behaves as expected with at least a dry run.
   Protocols that are no longer required can be removed from the protocol folder and stored in an “archive” sub-folder on RoboSep™ or on your networked computer.

4.3 Accessing Reports and Log Files

RoboSep™ stores usage reports (Section 2.4) as well as log files containing more detailed diagnostic information. One report file is generated for each day that RoboSep™ is run. Log files may be useful to an STI designated service technician to assist in troubleshooting. One log file is started every time RoboSep™ is started.

To access report files: Go to the reports folder and then go to the appropriate year and month to view the reports listed by date. The files have the format Report_DDMMMYYYY.txt.

To access log files: Go to logs folder. The files have the format robosep.log.XXX, where .XXX = .txt for the most recent log file, .1 for the next most recent and so on. To identify the log file corresponding to a given run it is necessary to know the time and date of that run. The precise information is available in the corresponding report file.

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5. Care and Maintenance

5.1 General Considerations

RoboSep™ is designed to avoid any cross-contamination of the samples or reagents manipulated during the experiments. In addition, RoboSep™ can be operated if desired within a biocontainment hood to maintain sample and reagent sterility. To ensure that RoboSep™ performs as expected regarding these aspects, it is the responsibility of the operator to maintain a clean and uncluttered environment. When using RoboSep™, as during any research experiment, it is essential to observe good laboratory practices, as described by your institution or company.

5.2 Daily Maintenance

1. Wipe down all exposed surfaces with an alcohol swab.
2. Verify that the hydraulic fluid bottle is full.
3. Wipe down the surfaces of the stainless steel tip head that hold the pipette tips (Figure 7). This tip head can accumulate a thin film of plastic from repeated loading and unloading of pipette tips that will degrade the ability of the tip head to seal adequately with the pipette tips.

5.3 Cleaning RoboSep

The preferred method to clean and disinfect RoboSep™ is to lightly spray 70% Ethanol or 70% Isopropanol on the instrument's external surfaces, and wipe it off with a soft and clean paper towel. RoboSep™ can also be wiped down with a dilute bleach solution (e.g. 1 in 10 dilution of 5% sodium hypochlorite solution), but should then be wiped clean with water.

For the touch screen, it is recommended that the 70% isopropanol be sprayed on a soft and clean paper towel, prior to wiping down. Excessive direct spray on the touch screen may cause fluid to seep behind the external surface and into the electrical components. Excess fluid should not pool at the margins of the touch screen.

Note: RoboSep™ is resistant to spills, but it is important to avoid spilling water inside the instrument through openings in the work surface such as around the carousel bearing column and the optical sensor opening.

If accidental spilling of biological material occurs in the carousel area of the instrument and a more thorough cleaning is needed:

- Unload and remove the carousel (Figure 18);
- Disinfect the carousel and magnets with dilute bleach solution and then rinse well with water;
- Rinse with distilled water;
- Disinfect the spill with dilute bleach solution. Dispose of clean-up material according to local regulations;
- Rinse the work surface tub with distilled water;
- Clean with 70% Ethanol.

5.4 Replacing the Fuses

The two fuses are located at the bottom right side of the instrument, next to the power supply outlet and the power switch. If RoboSep™ does not turn on when plugged in and the power switch is activated, the fuses may need to be replaced. To replace the fuses:

- Disconnect the power cable from the power source;
- Disconnect the power cable from the instrument;
- Open the fuse box and examine the fuses;
- Replace the faulty fuse(s). Always use Type T 5 x 20 mm fuses rated 4A, 250V;
- Reinsert the fuse box containing the new fuse(s) in its slot. Press gently until it snaps into place;
- Reconnect the power cable to the instrument, then to a grounded power source.

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6. Troubleshooting

RoboSep™ will present error messages to help diagnose some types of problems that may occur during use. Please record the message before calling technical support (Section 10: Contact Information). The following tables address other potential issues that are not flagged as errors.

Problem	Potential Cause	Solution
RoboSep™ screen does not turn on. No sound, movement, or sign of activity has been noticed 30 seconds after powering up the instrument (fails to start up).	Faulty fuse.	Check that the fuses are correctly installed as explained in the “Care and Maintenance” section of this manual. Replace fuses.
	No power to outlet.	Check that outlet is active by connecting a known working device, such as a lamp.
Operating system boots up but RoboSep™ fails to fully initialize.	Power switch not left off long enough. It takes up to 10 seconds for the electronics to fully reset after the power switch has been turned off.	After shutdown, turn off power switch and count to 10 before turning the power back on.
RoboSep™ won’t resume a paused run.	Lid up. RoboSep™ will not run if the lid is in the raised position.	Lower lid and press resume on screen.
RoboSep™ won’t shut down because you can’t load the basic shutdown protocol.	Previous run not complete or needs to be unloaded.	Let run finish. Press unload button on the Sample Processing screen.
Reagents left in tips.	RoboSep™ leaves residual volume in tips when pipetting small volumes.	This is normal operation and is required to meet the accuracy requirements for low volume reagent addition. The residual volume is 20 µL or less.
Missed tip pick-up.	Tip rack not placed properly on carousel.	Make sure that tip rack is seated properly by pushing down firmly on the outside of the exposed portion.
	Robotic arm or carousel was bumped during operation.	Only operate with lid down.
Tips not well aligned with tubes.	Positional calibration is required.	Contact STI technical support.
Tip rack separates at snap joint when removing cap.	Excess force applied at this joint by mistake.	Ensure only top cap is removed.
Missed tip stripping action.	Tip stripping arm not moving.	Arm is out of position. Power down the instrument, open the lid and pull the tip stripping arm out. Restart RoboSep™.
	Tip stripping arm not fully engaging tip head.	Contact STI for calibration.
Priming step missing or incomplete: No water ejected from tip head during priming step prior to run.	Connections in hydraulic system are leaking air.	Make sure the connection between the hydraulic fluid bottle and tubing is seated correctly by disconnecting and reconnecting firmly.
	Hydraulic fluid bottle is empty.	Refill bottle.

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7. Specifications

- Capacity:
- Labels and separates up to 4 samples simultaneously
- Up to 8 x 10^9 total cells (four samples of up to 2 x 10^9 cells each).
- Sample volume: from 250 µL to 8.5 mL for each sample.
- Pipetting range: 12.5 µL to 5 mL (accuracy: volume variations <10% for all the pipetting range)

- Dimensions:
- Height with lid: 55.6 cm (21 inches)
- Width: 70.7 cm (27 inches)
- Depth: 39.2 cm (15 inches)
- Weight: 26 kg (57 lb.)

- Power Requirements:
- Electrical supply 100-120/220-240 V ac, 50/60 Hz, 260 W
- uses two 4A, 250V, 5 x 20 mm Type T fuses

- **Conditions for Operation:**
  - Temperature 10°C to 30°C. Relative humidity 20-85% (non-condensing). RoboSep™ is not specified to be used in a cold room (4ºC, 39ºF).

- **For Indoor Use:**
  Certifications
  - Pollution degree 2
  - Installation category II
  - Altitude 2000m

CE and CSA certified.

RoboSep™ is intended for research use only.

8. RoboSep™ Spare Parts and Accessories

Product Name	Catalog #
Additional One-Year Warranty	20200
RoboSep™ Service Rack	20101
Hydraulic Fluid Bottle and Tubing	20102
RoboSep™ Buffer (250 mL)	20104
EasySep® RBC Lysis Buffer 10x Concentrate (100 mL)	20110
RoboSep™ Tip Racks (1 box of 8 racks)	20105
Ethernet Cross-over Cable	20106
RoboSep™ Carousel	20107
“The Big Easy” EasySep® Magnet	18001

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9. Warranty

Limited warranty to original purchaser:

RoboSep™ (the "Product"), as supplied and distributed by StemCell Technologies Inc ("STI") and delivered new to the original purchaser, is warranted by STI against manufacturing defects in materials and workmanship for the following limited warranty period: one (1) year parts and labor.

This limited warranty begins on the date of installation, and does not include transportation, removal or reinstallation. Warranty repairs must be performed by a STI authorized service center. Transportation of the Product to and from the service center is the responsibility of the purchaser.

STI will repair or replace the Product, at STI's option and at no charge with new or reconditioned parts, if found to be defective during the limited warranty period specified above. The Product must be returned during the warranty period with transportation charges prepaid to STI's designated service center. Prior to returning any Product for warranty service, the purchaser must contact STI for problem determination and service procedures. STI does not warrant uninterrupted or error-free operation of the product. All replaced parts and Products become the property of STI and must be returned to STI. Replacement parts and Products assume the remaining original warranty, or ninety (90) days, whichever is longer.

This limited warranty covers manufacturing defects in material and workmanship encountered in normal use of the Product and shall not apply to the following, including, but not limited to: damage which occurs in shipment; application and uses for which the Product was not intended; failures or problems which are caused by Products or equipment not supplied by STI; accidents, misuse, abuse, neglect, misapplication; fire, water, lightning or other acts of nature; incorrect electrical voltage, fluctuation or surges; damage caused by improper or faulty installation; improper connection with any peripheral; Product alteration or modification; improper or unauthorized repair; cosmetic damage or exterior finish; failure to follow operating instructions, customer adjustments, maintenance and environmental instructions that are covered and described in the user manual; use of non-STI or unauthorized parts, supplies, accessories or equipment which damage this Product or result in service problems; failure or problems due to incompatibility with other equipment.

STI is not liable for any damage to or loss of any data or other information stored on any media contained within the Product, or any non-STI product or part not covered by this warranty. Recovery or reinstallation of data or other information is not covered under this limited warranty.

In no event shall STI be liable, whether in contract or tort (including negligence) for damages in excess of the purchase price of the Product, or for any indirect, incidental, special or consequential damages of any kind, or loss of revenue or profits, loss of business, or other financial loss arising out of or in connection with the ability or inability to use the Product, to the full extent these damages may be disclaimed by law.

StemCell Technologies Inc makes and/or authorizes no other warranty except as is specifically described above. No additional warranties may be granted orally or in writing by any representative, nor implied by or inferred from the terms above.

Extended Warranty
An optional annual limited warranty extension for up to 2 years can be purchased with the same conditions as above.

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10. Contact Information

For customer service, technical support, or other information, please contact:

USA and Canada:

1.800.667.0322

email: info@stemcell.com

Other regions:

1.604.877.0713

email: info@stemcell.com

Head office:

StemCell Technologies Inc

570 West Seventh Avenue, Suite 400

Vancouver, BC, V5Z 1B3

Canada

CSA INTERNATIONAL

Certificate of Compliance

Certificate: 1660865 **Master Contract:** 227130

Project: 1660865 **Date Issued:** 2005/04/04

Issued to: **StarFish Medical**
555 Ardersier Rd, Unit 5
Victoria, BC V8Z 1C8
Canada
Attention: Mr. Fabio De Pasquale

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US'

C US

Issued by: Stephane Poutissou, P. Eng.

Authorized by: Ken Rutledge, Product Group Manager

PRODUCTS

CLASS 8721 04 - LABORATORY EQUIPMENT - Electrical
CLASS 8721 84 - ELECTRICAL EQUIPMENT FOR LABORATORY USE - Certified to US Standards

Blood Separator, Model RoboSep, rated 100-120/220-240 V ac, 50/60 Hz, 260 W.

Note: The above model is Equipment Class I, Pollution Degree 2, Installation Category II.

The 'C' and 'US' indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the U.S., respectively. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL, i.e. National Recognized Testing Laboratory, is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.

DQD 507 Rev. 2004-06-30

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CSA INTERNATIONAL

Certificate: 1660865 **Master Contract:** 227130

Project: 1660865 **Date Issued:** 2005/04/04

APPLICABLE REQUIREMENTS

CAN/CSA-C22.2 No. 61010.1-04 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements

UL Std. No. 61010-1 (2nd Edition) - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements

CONDITIONS OF ACCEPTABILITY:

- The equipment is supplied with an approved power supply cord set or power supply cord with plug that is acceptable to the authorities in the country where the equipment is to be used.

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